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See OMB Statement on reverse

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION, Federal Y2K Biomedical Equipment Clearinghouse
Additional Information Request Form – Product Status Is On A Web Page – FORM FDA 3470

Please verify and correct, or provide any missing information and return as indicated on the instruction page.
For detailed instructions, please refer to the appropriate line number on the **BACK** of this form.

Line #	Manufacturer Information	
1.	Manufacturer Name	
2.	Division *(see instructions on the back of this form)*	
3.	Enter Your FDA Assigned Owner/Operator Number	
	Contact Information	
4.	Y2K Contact's Name *(First and Last)*	
5.	Y2K Contact's Street Address	
6.	Y2K Contact's City, State/Province, and Postal Code	
7.	Y2K Contact's Country	
8.	Y2K Contact's Telephone	
9.	Y2K Contact's Fax	
10.	Y2K Contact's Email	
	Y2K Status Information	
11.	Web (URL) Address	
12.	Our records indicate that your company's current Y2K Status is:	**PRODUCT STATUS IS ON A WEB PAGE**
13.	Does this Web-site reflect all products that might still be in use? *(This includes all discontinued and obsolete products that might still be in use.)*	☐ **YES** ☐ **NO** *(If NO, please update your web site to include the data elements identified in Line #14.)*
	Additional Information	
14.	Following are the data elements that should be included for each product with a date-related problem listed on your company's web site. Refer to the instructions on **Product Problem – FORM FDA 3469A** for specific information about each element. • Trade or Brand Name • Model Number(s) • Original Manufacturer *(Name of the manufacturer under which this product was originally marketed.)* • Serial Number(s) • Date-Related Problem • Solution • Solution Date • User Action Necessary	

INFORMATION CURRENT AS OF 2/24/2000

Federal Y2K Biomedical Equipment Clearinghouse
Instructions – FORM FDA 3470

This form has been filled-in with the information your company has provided, if applicable. Please verify and correct, or provide any missing information and return as indicated on the instruction page.

If you have questions about completing this form or the Federal Y2K Biomedical Equipment Clearinghouse please call 1-877-744-1522 between 8:30am and 5:00pm Monday through Friday, Eastern Time or Email the Y2K Clearinghouse at y2kstatus@bah.com. You may also fax your completed forms to 1-301-881-1848.

Line Number Key

Manufacturer Information	
1. Manufacturer Name	Name of the Manufacturer submitting the product information.
2, Division	Name of the Division, if this report is for ONE specific division. Complete ONE form for each division that manufactures biomedical equipment. Please leave blank if you are reporting for the entire company.
3. Enter Your FDA Assigned Owner/Operator Number	If the Manufacturer submitting Y2K status information is FDA regulated, please enter your FDA assigned Owner/Operator Number.
Submitter/Contact Information	
4. Y2K Contact's Name *(First and Last)*	First and Last Name of the Y2K contact for the manufacturer.
5. Y2K Contact's Address	Street address of the Y2K contact.
6. Y2K Contact's City, State/Province, and Postal Code	City, State/Province, and Postal Code of the Y2K contact.
7. Y2K Contact's Country	Country location of the Y2K contact.
8. Y2K Contact's Telephone	Telephone number of the Y2K contact.
9. Y2K Contact's Fax	Fax number of the Y2K contact.
10. Y2K Contact's Email	Email address of the Y2K contact.
Y2K Status Information	
11. Web (URL) Address	Manufacturer provided a Uniform Resource Locator (URL) Address. This address should take users directly to the Y2K status information for the reporting company.
12. Our records indicate that your company's current Y2K status is:	Confirm that the submission type identified is correct: ***Product Status Is On A Web Page*** – Manufacturer provided a Uniform Resource Locator (URL) Address that points to information on a company Web site providing Y2K status information.
13. Does this status reflect all products that might still be in use? *(This includes all discontinued and obsolete products that might still be in use.)*	Does the Y2K submission type listed on Line 11 & 12 reflect all products that might still be in use? This includes all discontinued and obsolete products that might still be in use. If NO, please update your web site to include the data elements identified in Line #14
Additional Information	
14. Additional Information	The data elements listed in this section should be included for each product with a date-related problem listed on your company's web site. Refer to the instructions on **Product Problem – FORM FDA 3469A** for specific information about each element.

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, search existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Year 2000 Coordinator (HFZ-Y2K)
Center for Devices and Radiological Health, FDA
9200 Corporate Boulevard
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

YEAR 2000 READINESS DISCLOSURE